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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/519,323 | 12/23/2004 | Hans Loibner | 4518-0107PUS1 | 9319 |

2292 7590 04/25/2007

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| EXAMINER | |
|---|---|
| WAGHRAY, ANURADHA | |
| ART UNIT | PAPER NUMBER |
| 1609 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 04/25/2007 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/25/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,323 | LOIBNER ET AL. | |
| | Examiner | Art Unit | |
| | Anu Waghray | 1609 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claim(s) 1, 3-16 and19-23 are, drawn to a method of preparation of a medicament.

Group II: Claim 2 is drawn to a method of treatment.

Group III: Claim(s) 17,18,25 and 26 are drawn to antibody.

Group IV: Claim 24 is drawn to a method of diagnosis.

The inventions listed as Groups I,II,III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-IV share a common technical feature, an antibody directed against a tumor associated glycosylation. This antibody cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. Blaszczyk-Thurin.et.al (Protein Engineering. 1996. 9: 447-459) teaches an antibody directed against tumor-associated glycosylation. In spite of having a common technical feature they differ for the following reasons. Group I comprises of preparation of a medicament containing an antibody directed against a

tumor associated glycosylation and treatment of cancer patient. Group II does not involve preparation of a medicament and treatment with the medicament instead it requires treatment to a patient by administering an antibody directed against a tumor associated glycosylation. Group III involves preparation of a pharmaceutical and a diagnostic agent that is different from Groups I and II. Group IV is drawn to a method of diagnosis, which is completely different from groups I-III that involve preparation of a medicament or a pharmaceutical agent or treatment. Therefore Groups I-IV differ from each other in spite of sharing the same technical features.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species share the common technical feature, an antibody directed against tumor-associated glycosylation and this element is known in the prior art. Blaszczyk-Thurin.et.al (Protein Engineering. 1996. 9: 447-459) teaches an antibody directed against tumor-associated glycosylation. In spite of having a common technical feature the applicant has to elect one of the following species.

The species are as follows:

Group I: Elect one of the aberrant glycosylation protein from Lewis X, Lewis B or Lewis-Y-structure, sialyl-Tn, Tn antigen, Globo H, KH1, TF antigen or an alpha-1,3-galactosyl epitope.

Elect one kind of monoclonal antibody: human, humanized or chimeric or murine

Group III: Elect the antibody in combination with a carrier or with labeling.

For Group I, the aberrant glycosylation proteins differ in their ability to bind to the said antibody and need to be elected. The monoclonal antibodies need to be elected because they are originating from different species.

For Group III, the method of cellular immune complex will differ if the antibody is combined with a carrier from that when an antibody is combined with a labeling.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Waghray whose telephone number is 571-270-3063. The examiner can normally be reached on Monday-Thursday,7.30AM-5.00PM,Est. alt.Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZACHARIAH LUCAS
PATENT EXAMINER